DG HEALTH ADVANCED RELIEF EYE DROPS- dextran 70, polyethylene glycol 400, povidone, tetrahydrozoline hcl solution Dolgencorp LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

DG Health Advanced Relief

Active ingredients

Dextran 70 0.1%

Polyethylene glycol 400 1%

Povidone 1%

Tetrahydrozoline HCl 0.05%

Purposes

Dextran 70.....Eye lubricant

Polyethylene glycol 400......Eye lubricant

Povidone.....Eye lubricant

Tetrahydrozoline HCl.....Redness reliever

Uses

- relieves redness of the eye due to minor eye irritations
- as a lubricant to prevent further irritation or to relieve dryness of the eye

Warnings

For external use only

Ask a doctor before use if you have narrow angle glaucoma

When using this product

- pupils may become enlarged temporarily
- to avoid contamination, do not touch tip of container to any surface. Replace cap after using
- if solution changes color or becomes cloudy, do not use
- overuse may produce increased redness of the eye
- remove contact lens before using

Stop use and ask a doctor if you experience

- eye pain
- changes in vision
- continued redness or irritation of the eye, or if the condition worsens or persists for more than 72 hours

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Instill 1 or 2 drops in the affected eye(s) up to four times daily.

Other information

Inactive ingredients

benzalkonium chloride, boric acid, edetate disodium, purified water, sodium borate, and sodium chloride



DG HEALTH ADVANCED RELIEF EYE DROPS

dextran 70, polyethylene glycol 400, povidone, tetrahydrozoline hcl solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-361
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DEXTRAN 70 (UNII: 7SA290 YK68) (DEXTRAN 70 - UNII:7SA290 YK68)	DEXTRAN 70	0.1 g in 100 mL	
TETRAHYDRO ZO LINE HYDRO CHLO RIDE (UNII: 0 YZT43HS7D) (TETRAHYDRO ZO LINE - UNII:S9 U0 25 Y0 77)	TETRAHYDROZOLINE HYDROCHLORIDE	0.05 g in 100 mL	

POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) (POLYETHYLENE GLYCOL 400 - UNII:B697894SGQ)	POLYETHYLENE GLYCOL 400	1 g in 100 mL
PO VIDO NE, UNSPECIFIED (UNII: FZ989GH94E) (PO VIDO NE, UNSPECIFIED - UNII:FZ989GH94E)	POVIDONE, UNSPECIFIED	1 g in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
WATER (UNII: 059QF0KO0R)		
SODIUM BORATE (UNII: 91MBZ8H3QO)		
BORIC ACID (UNII: R57ZHV85D4)		
EDETATE DISO DIUM (UNII: 7FLD91C86K)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:55910-361- 01	1 in 1 CARTON	01/26/2020	
1	15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	01/26/2020	

Labeler - Dolgencorp LLC (068331990)

Registrant - K.C. Pharmaceuticals, Inc. (174450460)

Establishment			
Name	Address	ID/FEI	Business Operations
K.C. Pharmaceuticals, Inc.		174450460	manufacture(55910-361), pack(55910-361), label(55910-361)

Revised: 1/2020 Dolgencorp LLC